EXHIBIT 5

STATES UNITED COURT DISTRICT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	)	
This documents relates to:	)	
Salmons v. Purdue Pharma L.P. et al., MDL Case No. 1:18	)	MDL No. 2804
Flanagan v. Purdue Pharma L.P. et al. MDL Case No. 1:18-op45405;	)	No. 17-md-2804
Doyle v. Purdue Pharma L.P. et al, MDL Case No. 1:18-op-46327	)	

DEPOSITION OF CHRISTINA A. PORUCZNIK, PhD, MSPH
September 22, 2020 9:01 a.m.
Location: Utah of Utah School of Medicine
375 Chipeta Way, Suite A
Salt Lake City, Utah

Reported by:
HEIDI HUNTER, RPR, CSR

this case. I presume that they looked at my publications and gave me a call.

Q Do you have any reason why -- out of all the people that are working on opioid issues why they picked you?

MS. FUJIMOTO: Object to form.

A No. I think you'd have to ask them that.

MS. HENNING: This is Nicole Henning. Can we agree that Michi's objections are for all defendants?

MR. BILEK: Yes.

MS. FUJIMOTO: Great. Thanks for the reminder, Nicole.

BY MR. BILEK:

Q So how -- what was the circumstances of them hiring, when did that occur?

A I first had interaction with Ms. Fugimoto in winter of 2019, I believe. I'm trying to remember if it was before or after I broke my leg, and I think it was right around that time, and it was -- I think she was exploring my potential willingness to serve as an epidemiologist to really review the literature and make an assessment about what I thought the state of the science was.

Q And the -- so this was in the winter of 2019 you're contacted by Ms. Fugimoto. And what did you tell

her?

MS. FUJIMOTO: Object to form. Do not answer anything with regard to attorney-client or attorney work product privilege. No communications directly --

MR. BILEK: I'll restate that.

BY MR. BILEK:

Q I'm just asking the issues surrounding the retention. Was there any discussion on your background?

MS. FUJIMOTO: Same objection. I'm going to instruct her not to answer.

Tom, you can ask her when we contacted her, the method of communication, all of that, what she may consider her qualifications to be, all of that. But you can't get into the substance of our communications and you know that.

Q Let's approach it a different way. You were -- what is the Opioid Working Group?

MS. FUJIMOTO: Object to form.

A Can you be more specific?

Q Well, are you a member of an opioid working group that is involved in guidelines for the CDC?

A So are you asking about on my CV from 2016?

Q I'm going to ask a lot more about it than that, but you can start there, yes.

A Sure. So in 2016 I was chairman of the

working group through the Board of Scientific Counselors for the CDC on reviewing the CDC's proposed opioid prescribing guidelines for chronic pain in primary care.

Q And you still serve on that committee, right?

A Well, that committee is done. I still serve on the Board of Scientific Counselors for the National Center for Injury Prevention and Control.

Q And what does that group do?

A So that group serves as an external advisory board for that center at CDC.

Q And what is their primary responsibilities of -- what do they advise on?

A Since this is for the Injury Center at CDC, the Board of Scientific Counselors advises about scientific direction of research priorities and things like that for related to injury.

Q Well, isn't one of the big things that it's related to is opioid prescribing?

MS. FUJIMOTO: Object to form.

A Well, one of the big things that the injury center has been doing in recent years has been related to harms related to opioid drugs. They have had the guidelines. But remember CDC is not a regulatory agency.

Q But they send out advisories on to the medical

establishment, correct, on what the guidelines should be on prescribing opioids?

A They promulgated guidelines that was based on a synthesis of the evidence at that time and input from the various scientific stakeholders. And subsequent to that, they have issued many statements to help clarify what is in the guidelines, and then scientific reports based on analyses of public health data.

Q And these guidelines are directly related to opioids, right?

MS. FUJIMOTO: Object to form.

A Well, the title is about prescribing opioids for chronic pain in primary care.

Q And have you disclosed to anyone on the payments from McKesson in connection with your opioid work for CDC?

A As a member of the Board of Scientific Counselors, I complete the OGE 450 form each year, and I have not done that yet for this year. I disclosed in 2019 that I was working with McKesson.

Q So when did you disclose -- you did disclose that you were working for McKesson?

A Uh-huh.

Q When?

A When I last filed my OGE 450, which was --

group, you're also the chair of that, aren't you?

A Are you talking about the new recently formed workgroup?

Q Correct.

A Yes.

Q How many people on the new working group are there?

A I think 20-something, 23 maybe.

Q How many people are getting paid by the pharmaceutical industry?

MS. FUJIMOTO: Object to form.

A I do not know the answer to that.

Q Has there been -- as a chairman, have you done any investigation of how many people the pharmaceutical companies have hired?

MS. FUJIMOTO: Object to form.

A I have not.

Q Is there -- do you see any problem taking -- working for the opioid pharmaceutical companies while you're serving as chair of this advisory group?

MS. FUJIMOTO: Object to the form.

A When the work -- for each workgroup meeting there are disclosures. So that as we call the role, then people re-announce their disclosures. And in order to have subject-matter experts from various areas, you

know, many of whom might have had research grants or have been on pharmaceutical speakers' bureaus in the past, for a workgroup such as this, the conflict of interest rules are not as maybe strict as one would consider for a federal advisory committee.

And so the way that we manage such potential conflicts would be that in -- on a day when we're discussing something that is more related to what somebody might have had funding for in the past, then that person would be recused from that part of the discussion.

Q Well, you understand -- you're getting -- you're being retained by McKesson, right?

A I've been retained by McKesson to do an evaluation of the scientific literature about the epidemiology of neonatal abstinence syndrome.

Q I mean, do you think that your role as chairman as the advisory committee to the CDC had any role in you being hired by McKesson?

MS. FUJIMOTO: Object to form.

A You'd have to ask them.

Q What do you think?

MS. FUJIMOTO: Object to form.

A It's on my CV. This was information of which they might have been aware. I have also been recruited

includes prescribing for chronic pain by women?

A Sorry, could you repeat that? A lot of things happened at once.

Q Well, one of the things you're concerned about in the guidelines is prescribing pain -- prescribing opioids to women for chronic pain during the period that they're pregnant?

MS. FUJIMOTO: Object, form.

A The primary audience for the guidelines is primary care management, and pregnant women constitute a special population who are not part of the target audience for the -- from those guidelines.

Q Who's the target audience?

A Adults with chronic pain who are being managed in primary care.

Q Aren't some of those people going to be pregnant women?

MS. FUJIMOTO: Object to form.

A Certainly women can become pregnant.

Q Isn't it true that one of the issues that you're considering on in connection with your scientific advisory is the question of the risk benefits of neonatal abstinence syndrome --

MS. FUJIMOTO: Object to form.

Q -- in connection with prescribing opioids?

MS. FUJIMOTO: Same objection.

A The focused population for the guidelines does not include pregnant women.

Q Well, it includes -- it includes all adults, right?

A It includes adults who are being managed for chronic pain in primary care. It specifically does not include pregnant women, does not include cancer patients, does not include pediatric populations.

Q I think we'll get to some documents and maybe refresh your memory a little bit on that. But let's go -- but the response to the question here is -- would you read the next sentence.

MS. FUJIMOTO: What page are you on, Tom?

MR. BILEK: Right after financial conflicts of interest.

MS. FUJIMOTO: Does it have a page number?

MR. BILEK: I just downloaded this from the CDC. It doesn't really have page numbers on the downloads.

THE WITNESS: It's page 6.

MS. FUJIMOTO: All right.

BY MR. BILEK:

Q Would you read that, please.

A "Generally you may not work a committee that

recommended prescribing, right?

MS. FUJIMOTO: Object to form.

A The 2016 guidelines are for chronic -- opioid prescribing for chronic pain managed in primary care. The question that is going to be -- that is coming up, there's been new research evidence, and there is consideration on whether there will be modifications to the guidelines.

Q And what's the modifications that are being considered?

A I don't know.

Q You're the chair of the group. What -- why don't you know?

MS. FUJIMOTO: Object, form.

A The group has not met.

Q Why has the group not met?

A It just hasn't. It has only recently been convened. And trying to schedule a lot of people to have a meeting, particularly during a pandemic, is a challenging thing.

Q I agree with that, but somehow we're finding a way here. Why aren't there -- like, you're the chair. Why aren't you trying to do like Zoom conferences or something like that?

MS. FUJIMOTO: Object to form.

MS. FUJIMOTO: Object to form.

A I do not believe that that is part of the charge of the workgroup.

Q So these guideline recommendations that were here in this report, were all of these made?

MS. FUJIMOTO: Object to form.

A Say that again. I didn't understand the question.

Q You've got, looks like, how many guidelines? Twelve guideline recommendations in here.

Were these guidelines -- what happened to these guideline recommendations?

A So ultimately the observations from this workgroup were used to -- probably to edit and modify a bit on wording and to provide the recommendation categories and evidence types that were ultimately in the CDC prescribing guidelines for chronic pain in primary care.

Q Let's turn to your qualifications for a little bit. You're not a medical doctor, correct?

A I am not a medical doctor. I have a Ph.D. in epidemiology.

Q And you are not qualified to diagnose NAS?

A As an epidemiologist, I do not diagnose anything, including neonatal abstinence syndrome.

Q And you're not qualified to review -- well, strike that.

Not only are you not qualified to diagnose NAS, you would not hold yourself out as an expert as far as questioning any individual doctor's diagnosis of NAS?

MS. FUJIMOTO: Object to form.

A As an epidemiologist, I would not get in between a doctor caring for a particular patient.

Q And this would include diagnosing NAS?

A As an epidemiologist, I would not get in between a doctor diagnosing a patient with NAS.

Q You have never published any literature on the use of opioids in newborns or pregnant women?

MS. FUJIMOTO: Object to form.

A I believe that is a correct statement.

Q You have never published any peer-reviewed literature in the clinical outcomes resulting from prenatal or postnatal opioids?

A I have not published on clinical outcomes related from prenatal or postnatal exposure to opioids.

Q You have not published on the mechanisms associated with analgesia tolerance or withdrawal?

A I have not --

MS. FUJIMOTO: Object to form.

A I have not published on the mechanisms

associated with opioid analgesia tolerance or withdrawal.

Q You have not published any peer-reviewed article in the development of the fetal neonatal brain with or without exposure to opioids and/or other recreational drugs?

A I have not published in the peer-reviewed literature about fetal brain development related to exposure to anything, including opioid drugs, other drugs of use or any other substance.

Q You have not done any peer-reviewed study on neuro-development outcomes following prenatal opioid exposure or prenatal alcohol or other prenatal drugs or their fetal brain development in pregnancy?

A That is correct. I have not published anything about neuro-development following exposure to substances in~utero.

Q Let's -- are you aware of states trying to pass legislation to limit the prescribing of opioids?

MS. FUJIMOTO: Object to form.

A I believe that I recall that Ohio had a regulation. I cannot -- I don't remember if it was a law or a regulation about limiting opioid prescribing, particularly in the emergency room or an urgent care situation. I can't be any more specific than that.

guidelines.

Q So you didn't even look at the NAS issue in connection with the guidelines?

MS. FUJIMOTO: Object to form.

A None of the guideline statements are about management of pregnant women.

Q Why not?

MS. FUJIMOTO: Object to form.

A The audience for the guidelines is managing chronic pain in primary care.

Q Well, I mean -- I'm going to be honest with you, Doctor, I'm confounded by this of the issue of why pregnant women aren't being considered as an adult that is being prescribed opioids?

MS. FUJIMOTO: Object to form. Is there a question?

Q Yeah. Why aren't you doing it?

MS. FUJIMOTO: Object to form. Go ahead.

A So this is going to be a little bit rambly but patient with me for a second because it fits.

One of the heads headlines in the New York Times this morning was about vaccines for coronavirus for children may not be available at the same time as they are for adults. And the reasoning for this is that children are not included in clinical trials the same

way that adults are.

As we were reviewing the evidence considered as a part of the workgroup for chronic pain prescribing in primary care, turns out that pregnant women are another group that are frequently not included.

They're excluded from research studies, which means that the -- they were not necessarily a part of the studies that we were reviewing. They're considered a special population.

Q Well, was the harm of -- possible long-term harms of a child born with NAS, was that considered?

A So a child born with NAS is not part of the population intended to be addressed by the guidelines.

Q Do you have any evidence -- the plaintiffs' experts have determined there are approximately 500,000 NAS births in the last 18 years. Do you have any disagreement with those numbers?

MS. FUJIMOTO: Object to form and foundation.

A So neonatal abstinence syndrome is a diagnosis. And in order for that diagnosis to have been made, then there needed to be some sort of clinical suspicion, and then proceeding through the steps of applying a case definition. And so before I really accept that number, I would want to be sure about consistent application of a case definition over space

Q So you don't see any value in trying to -- these states passing laws to reduce the number of prescriptions that are being written?

MS. FUJIMOTO: Object to form.

A I am concerned about legislation that might interfere with patients getting healthcare that they and their doctors think is appropriate for them.

Q Let's go to the second page of Exhibit 6.

A Okay.

Q The last paragraph says, "Improving prescribing practices for the way pain is treated is one avenue to help prevent misuse, addiction, overdose while ensuring legitimate access to pain management."

Do you see that?

A I see that sentence.

Q Do you agree with that statement?

MS. FUJIMOTO: Object to form.

A I think that improving prescribing practices in the way we treat pain is one avenue to help prevent misuse, addiction, and overdose while ensuring legitimate access to pain management.

Q Do you agree that using opioids to treat acute pain can lead to long-term use?

A The literature suggests that physical dependence on opioids can begin relatively quickly, such

marketing to encourage people to smoke.

Q Do you think that pharmaceutical companies have done a lot of marketing to encourage use of opioids?

MS. FUJIMOTO: Object to form.

A I think pharmaceutical companies do a lot of marketing. And yet, as controlled substances, access to opioids is still something that happens in a doctor-patient relationship.

Q But we know that -- we know several things about this opioid epidemic, we know that there are prescriptions being diverted, right?

MS. FUJIMOTO: Object to form.

A I -- I'm thinking about what data there are about prescription diversion. I can't dispute that it happens and yet I also can't estimate how much that there might be.

Q I mean, was the issue of diversion of prescriptions ever considered in your -- any of your two working advisory groups?

A I'm going back to the observations. I'm not really looking at these other exhibits. I'm just trying to pull out the one that we already looked at of the observations from the workgroup, because I don't believe any of the guideline statements beyond those about safe

Q Well, you'd -- I mean -- as you probably know, I've got a few studies here that we could go over. But the issue, you would agree, that there were a number of studies that have been written which questioned the prescribing of opioids for long-term chronic pain?

MS. FUJIMOTO: Object to form.

A I believe that there are such studies in the literature. If you want to talk about a specific one, we could talk about that. Because every study is subject to strengths and limitations and needs to be evaluated on its merits.

Q Right. But when the CDC is doing these guidelines, I mean isn't one of the things that should be considered of what the benefits are of prescribing the opioid for long-term chronic pain?

A There's a guideline -- I mean, the idea of risks and benefits and having conversations and considering possible risks and benefits is woven throughout the CDC guidelines.

Q And if the benefit for long -- treatment long-term chronic pain is negligible, wouldn't that be a big affect on your guideline?

MS. FUJIMOTO: Object to form.

A The -- so guidelines are intended to help be a decision framework to be applied within a doctor-patient

relationship. So it's something that individuals need to work out within specific instances.

Q Was there -- have you done any investigation on the differing effects that opioids have on women versus on men?

A I do not believe I've published anything about that research question.

Q I know, Doctor, you haven't. Right now I'm pretty much -- I know what you've done and what you haven't. What I'm -- what I'm asking is: In the committee, did you guys ever consider the different -- differences between -- how opioids react between women and men?

MS. FUJIMOTO: Tom, I'm going to object to that admonition. She answered the question and you don't mean to be snide to her.

And this is a different question. So answer this different question, Doctor.

A Part of evaluating risks and benefits or benefits and harms in a particular doctor-patient interaction could include considerations of sex differences or size differences, you know, any particular features of that patient. I do not believe any of the guideline statements call out separate recommendations based on patient sex.

Q I'm asking you: Do you recall any investigation by either the scientific panels on the differing effects of opioids on women versus men?

MS. FUJIMOTO: Objection to form, asked and answered.

A Sorry. Someone was trying to come into my conference room.

So our charge was to evaluate the evidence related to the guideline statements. And as none of the guideline statements were differential by patient sex, I do not recall such discussions.

Q Well, on the committee, was the committee, your scientific advisory committee that you chaired, were they limited to only looking at guidelines that came down from somewhere else that were being proposed, or were you able to have a role in drafting the appropriate guidelines?

A For the Opioid Guideline Workgroup, we were not drafting guidelines. We were making observations on the proposed guidelines as to the level of evidence.

Q Did you ever decide that: Hey, we need to investigate this type of issue?

MS. FUJIMOTO: Object to form.

Q Do you recall anything -- anything new to the attention of the -- either the CDC or the main group?

section on literature on the impacts of NAS and long-term developmental impacts.

BY MR. BILEK:

Q Now, is it -- the way I read your report is that you don't know whether -- your opinion is you don't know whether there's going to be a long-term impact on opioid exposure in utero; is that correct?

MS. FUJIMOTO: Object to form.

A My first sentence is, "The long-term impacts of opioids exposure in utero on child development are uncertain and variable."

Q And so the issue is you don't know what the long-term effects are going to be, long-term developmental effects?

MS. FUJIMOTO: Object, form.

A I think that the -- based on the evidence in the literature now, that long-term impacts are uncertain and variable.

Q Is it something that you think that there should be more study on the long-term developmental impacts on children born with NAS?

MS. FUJIMOTO: Object to form.

A I think that that is a research area that probably a lot of people are working on now. And for any study of that, I think it's really important to come

back to the fundamentals about measurement of exposures, and measurement of outcomes, and consideration of potential confounders.

Q Do you think it should be studied more or less?

MS. FUJIMOTO: Object, form.

A I am sure that it is being studied. As long as it's a research question, then, sure, people are going to study it.

Q What's your understanding of what the plaintiffs are seeking in this lawsuit?

A That they are seeking to define a class of -- that would be comprised of babies born with NAS. And that one of the potential ideas for what to do with that class would be somewhat long-term, like registration into a registry with potential follow-up.

Q So one of the issues in the -- I will represent to you is medical monitoring of children that were born with NAS. Is that something that you think is appropriate or inappropriate?

MS. FUJIMOTO: Object to form.

A Well, I think that the growth and development of all children is a good idea to pay attention to.

Q Including children born with NAS, right?

A Children born with NAS are part of all

children, yes.

Q Now, is the -- one of the other things I would tell you that the plaintiffs are seeking is an appointment of a science panel to study the issue of the affects of the NAS on children.

Is that something that you agree with or disagree with?

MS. FUJIMOTO: Object to form.

A I think the notion of a scientific advisory board or a science panel could be a reasonable one.

Q Now, when you're going on -- I note in here that you cited to -- let's see here, on your long-term effects. You had a couple of studies that you cited to on your long-term effects.

There it is. On page 10, you state: "A systemic review and meta-analysis of neurobehavioral outcomes following in~utero exposure to opioids found only five studies that had quantitative measures of outcomes. Based on those five studies, the conclusion was that there were no significant impairment compared to nonexposed children."

Do you see that?

A I see those two sentences.

Q Is that a big part of what you're relying upon that the children born with NAS do not have long-term

developmental problems?

MS. FUJIMOTO: Object to form.

A I think that the studies that have attempted to quantify have used different measures, have had variable exposure assessment. And that's one of the things that was noted, for example, in the Conradt paper about that the exposures are heterogeneous, treatment was heterogeneous. And so trying to collect these babies into a recognizable class and then say that they're all the same is problematic.

Q I understand that, Doctor. I mean, what I'm getting at, the Baldacchino Arbuckle is what you're relying upon that you believe that that there are no significant impairments compared to nonexposed children, right?

MS. FUJIMOTO: Object to form.

A That was the -- the conclusion from that study, which is part of what informed my report, was that there was no significant impairment compared to nonexposed children.

Q And that study was a key part of what your reliance is, right?

A That study is part of what my report relied upon.

Q Have you looked at whether that study was

numbers within the" --

MS. FUJIMOTO: Object.

Q -- "additional studies are needed to improve the power of a future meta-analysis to produce significant results."

Do you see that?

MS. FUJIMOTO: Object to form; misreads document and misstates testimony.

A I see those sentences.

Q Okay. The point is they're saying that there needs to be more future meta-analysis, correct; more studies, which you agree with, right?

A Well, virtually every research study in the conclusion says: More research is needed on this topic. And in particular, something that is a meta-analysis relies on the existence of other studies, so that then the people who are doing the meta-analysis can combine the previous studies to come up with a single measure of effect.

Q I understand. But they were more precise in this one. They said that we need longitudinal studies on children over the age of five, correct?

MS. FUJIMOTO: Object to form.

A Their sentence says -- weirdly starts with the word "and" -- "And longitudinal studies are needed to

determine if any neuropsychological impairments appear after the age of five years and to help investigate further the role of environmental risk factors on the effect of core phenotypes."

Q Would you agree with that conclusion that more longitudinal studies were needed for children over the age of five?

MS. FUJIMOTO: Object to form.

A Well, if you go back to their Table 3 where they're describing the populations of the studies that they were looking at for this, you know, they're all infants and preschool, which is the topic of this systematic review and meta-analysis is infants and preschool.

So, you know, I don't know if these authors are limited to that population because that's what data were available, and they would like to do something in the future with older children or not. But they didn't report on, you know, any that were older than age five, according to Table 3.

Q Well, you would agree, though, that this study, 2015 study, one of the things that we should look at is what happens as the child gets older, right?

MS. FUJIMOTO: Object to form.

A I think that if we're interested in outcomes

that may manifest in older ages than infant and preschool, then there need to be well-designed studies with precise exposure assessment and outcome assessment and ability to control for confounders to try and answer that research question.

MR. BILEK: Let's pull up Exhibit 56 and this will only take a minute and we'll take a lunch break.

MS. FUJIMOTO: Got it.

(PLAINTIFF EXHIBIT 56.)

BY MR. BILEK:

Q Can you identify what's been marked as Plaintiffs' Exhibit's 56?

A So this exhibit is an Erratum: "Neurobehavioral Consequences of Chronic Intrauterine Opioid Exposure in Infants and Preschool Children; a Systemic Review and Meta-analysis" from BMC Psychiatry in 2015, and it's by the same authors.

Q What does an erratum mean?

A It means that this is the like the worst day of their scientific lives and they made a mistake, and they are publically acknowledging it.

Q And it says, "Correction: After publication of this work, we became aware that during our entry of raw data in the Complementary Meta-Analysis Program, we transposed one of the columns of data. This meant the

values generated by all the meta-analysis and results produced in the published manuscript, including those displayed in Figures 2 to 7 and Table 4 were incorrect. We subsequently repeated the meta-analysis and updated the figures, table and manuscript to reflect the new results following this reanalysis.

"The new conclusions of the paper show significant impairments at significant level of p less than 0.05 for cognitive, psychomotor, and observed behavioral outcomes for chronic intrauterine opioid exposed infants and/or preschool children compared to nonopioid exposed infants and children."

Do you see that?

A I do.

Q What does that mean to you?

A It means that their -- in their analysis, they probably had something backwards, and so their initial findings were incorrect. And then when it was pointed out to them, helpfully by Dr. Nygaard, they went back and did a reanalysis and are presenting their new data, and so now they have -- so they have new tables and figures.

Q And what they found that was significantly -- to a significant level that there were cognitive, psychomotor, and observed behavioral outcomes for

A You know, I did not know about this erratum before today and it's -- here's the thing, the majority of papers in the literature do not have subsequent erratum, and so it's not -- like my expectation value would not be for every paper I look at to go look and see if there's a later correction.

And also, for many papers where there are corrections or erratums or updates, on what turns out to be like the face page, there will be a notation to say: Oh, there's something else that you should look at. And, you know, that wasn't there.

And I agree, I did not, you know, go searching to see if this author had published anything else that might contradict what they had previously published.

Q And the fact of the matter is, you have misstated in your report that -- on this study, that there are problems as a result of opioid exposure in the womb, correct?

MS. FUJIMOTO: Object to form.

A Actually, I take exception to that. Based on what I'm citing in my report, which was this -- their original document, then I'm -- I am stating their original conclusion correctly.

Now, there were -- you know, there was an erratum of which I was not aware that knowledge of which

might have changed that statement. But regardless, you know, my report is based on not only this paper, but, you know, several papers put together.

Q Well, for this statement on page 10, you only cite to this article, correct?

MS. FUJIMOTO: Object to form.

A For the statement in contrast, a systemic review and meta-analysis of neurobehavioral --

Q Yes.

A -- I am citing this particular study, because the previous paragraph was about a different study.

Q And if you were having -- if I were your peer review right now on your report, I mean, I'd point this out to you, and you'd have to fix this, wouldn't you?

MS. FUJIMOTO: Object to form.

A That's how science works.

Q And you would agree that this was not your best work right now, right?

MS. FUJIMOTO: Object to form.

A I agree that I did not go and searching to see if these authors had published anything else or if there had been an erratum published to this particular article.

Q And when you are saying that these kids are not developmentally challenged or that the science is

uncertain, I mean, this stuff has consequences, right?

MS. FUJIMOTO: Object to form.

A So I feel like you had two things in there of saying that there's no consequence or that the consequence is uncertain and then that has impact. And I think that that would come to a conclusion that's, you know, similar to the one that you were pointing out from the original Baldacchino article where they specify that the evidence is sparse.

Q Now, the fact that they've changed their conclusion, you're now going to rely on the fact that the evidence is sparse?

MS. FUJIMOTO: Object to form.

A I stated in my report that the evidence was sparse already.

Q And indeed, yesterday I got from your lawyer that you've now reviewed some more studies, correct?

MS. FUJIMOTO: Object to form.

A Do you mean the papers that they gave me yesterday and suggested that I look at because you like them?

Q Yes.

A I took a look at them last night.

Q And those studies were provided by your lawyer in response to stuff that I've done in these

depositions, right? That's your understanding?

MS. FUJIMOTO: Object to form.

A That is my understanding.

Q And those were, again, not reports that you independently reviewed or investigated to try to determine whether there are additional studies on long-term effects from being born with NAS?

MS. FUJIMOTO: Object.

A I believe that I had already cited at least one of them, and that I believe another one of them was published after I submitted my report.

Q But two more you do not cite your report, correct?

A If I go grab them, then I can compare it to my work cited list to be sure.

MR. BILEK: We can do that during lunch. Let's take a lunch break. Let's get started again in an hour. I think it's 12:15 there, so we'll come back at your time 1:15. Thank you.

(Recess from 12:13 to 1:12.)

BY MR. BILEK:

Q So let's revisit the mistake of missing the erratum to that study. Is it fair to state that you don't consider yourself -- I mean, let's look at how this could have happened. You do not -- your expertise

is not the study of NAS, right?

A That is correct.

MS. FUJIMOTO: Object to form.

Q And so before this deposition you were in the practice of reading studies on NAS, the causes, you know, the problems associated with NAS; is that correct?

A For -- like for the typical practice of my job, I would not necessarily read every study about NAS. If something came across that looked interesting I might read it, but I'm not systemically searching for studies about NAS.

Q Right. Because, again, this is not your expertise. It's not NAS. So it's not something that you're following closely or much at all, right? You're more concerned with issues -- addiction issues with adults, right?

MS. FUJIMOTO: Object to form.

A Actually, I disagree with that assessment that I wouldn't say that I'm more interested in addiction issues with adults either. As an epidemiologist, I'm really interested in about appropriate timing of exposure assessment, and how we're measuring exposures in populations.

Q But one of the things you never studied before you were contacted by McKesson in this case, you've

never been -- you've never studied the issue of NAS at all?

A I've never done my own research or published about NAS, that is correct.

Q And so to defend you a little bit, this issue of missing the errata is caused by the fact that you're not in the study of NAS?

MS. FUJIMOTO: Object to form.

A I've never published or done my own research about NAS. I think we agree about that.

Q And the extent of -- the primary reason why you've done research now in NAS is because you were contacted by McKesson, correct?

MS. FUJIMOTO: Object to form.

A I was asked to take a look at the literature and provide my opinion about exposure assessment and outcome assessment in studies relating to NAS as an outcome, and in particular to think about issues related to how we might define a class.

Q Well, the issue of how you define a class in this case has to do with issues intertwined with NAS, right?

A It has everything to do with issues of exposure assessment and outcome assessment, and if we can measure exposures specifically enough and outcome

specifically enough and with enough homogeneity to define a meaningful class.

Q And you would agree that in connection with your investigation that NAS can be caused by opioids?

MS. FUJIMOTO: Object to form.

A So neonatal abstinence syndrome is something that can be the result of exposures to multiple different substances, including opioids.

Q Now, going to long-term studies on -- well, let's -- I think that you now have reviewed the Yeoh study, this Cognitive and Motor Outcomes of Children with Prenatal Opioid Exposure, correct?

A That's one the studies that was sent to me yesterday and I took a look at it last night.

Q What's your opinion on that study, if anything?

MS. FUJIMOTO: Object to form.

A Is that study included among the exhibits?

Q I can make it. I'm just asking since you just reviewed it yesterday whether you had any opinions on it.

MS. FUJIMOTO: Object to form.

A So last night I reviewed several studies. And if I'm going to make comments about a specific one, I'd like to have it in front of me so that I make sure that

exposure was associated with lower cognitive scores. The largest difference was in between ages six months and six years."

Do you see that?

A I see that in the findings box.

Q Do you have any quarrel with this finding?

MS. FUJIMOTO: Object, form.

A My biggest concern with this study comes into the exposure assessment that was done in the source studies as it's described in this systematic review and meta-analysis, that they're limited to the data that were presented in the studies, and so their exposures here for how they measured prenatal opioid use are not specific.

So they're comparing groups that used heroin in conjunction with poly drug ingestion, methadone in conjunction with poly drug ingestion, and unspecified opioids.

So my biggest concern about this is that we have a pretty broad and not well-specified mix of exposures to these children during their fetal periods.

Q So your quarrel with the study is the study design, or is that what your -- what your concern is?

MS. FUJIMOTO: Object, form.

A I'm saying that trying to draw any inference

MS. FUJIMOTO: Object to form.

A Depending on their research question and the strength of the effect, one may be able to find a statistically significant finding with a really small number of people. It all depends.

Q So on the long-term -- so you're saying that you, yourself, on this study can draw -- you don't agree that this is evidence of possible long-term -- possible long-term effects stemming from prenatal opioid exposure?

MS. FUJIMOTO: Object to form.

A I think that this study has a place in the literature. And that as people are evaluating, you know, what can we see? You know, each study can contribute something, and it's accorded more or less weight in factors related to the quality and design and conduct in the study.

So I'm not saying that this should just be tossed out entirely. I'm saying that, as with any study, even a meta-analysis, that we need to, you know, look carefully at the exposure assessment and the outcome assessment to think about how much weight to give it into our analysis.

Q Would you agree that epidemiologists in your field would rely on a study such as this?

MS. FUJIMOTO: Object to form.

A I agree that epidemiologists would read a study such as this, and I think each person would draw her own inference from it.

Q Well, would this be something that you would find something that you would normally look at and rely upon in forming a conclusion on whether there are long-term problems resulting from -- resulting from opioid exposure in the womb?

MS. FUJIMOTO: Object to form.

A A study like this would fall into the full group of evidence that would be used to synthesize and draw a conclusion.

Q Now, your --

MS. ULLMAN: Tom, before you asked a next question, there's a person with a phone number area code 786 who I think is not mute. So if that is you, I would mute yourself.

MR. BILEK: It is somewhat exhausting it.

I don't think they muted themselves. I don't think they're on there, I think they're just billing.

Yep, that is my suspicio is correct, there's no one there. Is there any way -- well, I don't know.

MS. ULLMAN: I think you just can't see the icons on the phone. They may have well muted.

A We solved it.
Q It's a long day.
A For you too.
Q This is not easy, Doctor.
A Okay.
THE WITNESS: So Michi, do you have educational --
MS. FUJIMOTO: I have 17.
THE WITNESS: I grabbed the wrong one.
So this is, "Educational Disabilities Among Children Born with Neonatal Abstinence Syndrome." This is from the Journal of Pediatrics in 2018, and their conclusions were: "Results of this novel analysis linking health and education data revealed that children with a history of NAS were significantly more likely to have a subsequent educational disability."
Q This is the study you have reviewed?
A This is a study that I did review. I did not include on to the list of works that informed my conclusions. I didn't cite anything from it specifically, but it is something that I remember reading.
Q Why didn't you include it in your report?
MS. FUJIMOTO: Object to form. Go ahead.
A Honestly, I didn't give it very much weight.

Q Why not?

A So they were starting with children who have a history of NAS and comparing them to children not so identified, and then linking to special education services to see if it was more likely in one group or the other. And when I was thinking about -- again, about exposure and outcome assessment, that I felt like there was a lot of risk for bias in this study.

Q Why?

A Because I'm really concerned that the kids -- that there may be a differential chance of some being sent for screening for special ed services because they knew that this child had had a diagnosis of NAS. So to me, it felt like it was all wrapped up together.

Q So you -- your complaint with the study is that you can't -- did they say that they were -- there was this bias problem that you were identifying?

MS. FUJIMOTO: Object to form.

A So on the last paragraph on page 6 is where they start talking about limitations and that specific limitation is listed.

Q So what's your basis for that limitation that you're identifying when it's not in this study? Have you talked to the authors?

A I have not talked to the authors about this

done the same way for everyone. So those are good things.

But we don't know a whole lot. I mean, they don't report a whole lot about these prescriptions, just the fact that they happened, right? So we don't know about duration, you know, we don't know a whole lot of frequency. They do report if people had it in multiple trimesters. So I'm saying that they did a nice systematic job of exposure assessment.

Is it as precise as would have happened in an ideal prospective study, no. It's not a quarrel. It's an observation.

Q So, but one of the things to do that you would agree to try to evaluate opioid exposure to the fetus is to look at the prescription history of the birth mother, right?

A So that's -- I mean, looking at the prescription history of the birth mother is one possible way to try to assess exposure to opioids that came through medical interaction. It's not complete, because, of course, women might have had exposure to opioids in other ways that are not included on their medical records, and the medical record would rarely have information about how that woman actually took the medication.

this that's missing. But if we go to 2.7.4: "Central to the unique issues women face in pain management are the differences between men and women with respect to pain sensitivity, response to pain medication, and predisposition to clinical pain conditions."

Do you see that first sentence?

A I did see that first sentence.

Q Isn't it, when you're doing the guidelines, something that would make sense to be considering this issue between the differences between the sexes?

MS. FUJIMOTO: Object to form.

A I think that this is noted as a gap and a recommendation. Well, it looks like it's noted as a gap. And, you know, the recommendation of this task force is to consider men and women as different populations.

Q Let's go to the 2.7.5, the next page on pregnancy. Do you see that?

A I see 2.7.5 pregnancy, yes.

Q The statement says, "Managing pain in pregnant women is uniquely challenging because clinical decision-making must account for the pregnant mother and the developing fetus." Do you see that?

A I see that first sentence, yes.

Q Is that something that you would agree with?

MS. FUJIMOTO: Object to form.

A I think anyone would agree with that statement. So yes, I agree with that statement.

Q "Further complicating pain management in the peripartum period is the lack of CPGs for nonpharmacological treatments that may decrease the potential adverse outcomes for newborns associated with opioid therapy such as neonatal abstinence syndrome."

Do you see that?

A I see that sentence.

Q "Greater research into chronic pain management in pregnancy is needed." Do you agree?

MS. FUJIMOTO: Object, form.

A It seems like a reasonable statement to say that researching chronic pain management in pregnancy is a good idea.

Q Let's look at the next thing on Recommendation 1B says, "Counsel women of childbearing age on the risk of opioids in nonopioid medications in pregnancy, including risks to the fetus and newborns."

Do you see that?

A I do see that.

Q Do you agree that that's a recommendation that should be done?

MS. FUJIMOTO: Object to form.

A I think that counseling women of childbearing age on the risks of exposures to all kinds of substances is something that is already routinely done and is part of good clinical care.

Q Don't you think we should be specifically telling the women that if they have a prescription for opioids while they're pregnant that perhaps that their going to have a child with NAS?

MS. FUJIMOTO: Object, form.

A I think that discussing risks and benefits is an important part of everything prescription experience for opioids, for antibiotics, for decongestants.

Q Well, why is it that CDC guidelines that you're involved in not involved with this issue of recommendation of opioid prescription to pregnant women?

MS. FUJIMOTO: Object, form.

A The target population for the guidelines was managing chronic pain in primary care, not specifically pregnant women.

Q Pregnant women are people too, right?

MS. FUJIMOTO: Object to form, asked and answered.

Q I'm just not getting it. I mean, I'm just being honest with you. I'm not trying to be difficult with you. I'm not getting why the issue of pregnancy

include neonatal opioid withdrawal syndrome." Would you agree that that is a risk of taking opioid pain medications during pregnancy?

MS. FUJIMOTO: Object to form.

A I think that if you -- if your baby never had an opioid exposure, then they couldn't have neonatal opioid withdrawal syndrome. So having, you know, exposure puts you -- makes you eligible for that category.

Q Neural tube defects?

MS. FUJIMOTO: Your question?

Q Do you think that neural tube defects are a possible risk to your pregnancy?

MS. FUJIMOTO: Object to form.

A I think that they are citing that Broussard study about maternal treatment with opioid analgesics and the risk for birth defects with that statement.

Q Well, do you agree with this CDC guidance here that: Neural tube defects, "Serious problems in the development or formation of the fetus brain or spine, may be a possible risk to your pregnancy as a result of taking opioid pain medication"?

A Well, I think, since they have cited one, two above in the superscript, and if you go reference one is maternal treatment with opioid analgesics and risk for

Department of Agriculture and then kind filters down to the states and to the schools. And then the question of how it gets operationalized at a school level and -- you know, the people who are the program and the funding for the program probably have very little control over the actual operationalizing of the program and how kids might be stigmatized or not stigmatized by receipt of a school lunch, which you're probably going to say was nonresponsive.

But I think that there is potential to provide a service in a way that has respect for persons and can maintain dignity.

Q Actually, Doctor, I agree with you. So the issue of do you think there's a potential to assess children with -- that were born with NAS, to assess them such a manner in which they're not to be stigmatized?

MS. FUJIMOTO: Object to form.

A You're not going to believe this, but I can actually agree with you.

I made you smile, that makes my day.

Here's the thing, I think that a thoughtfully developed program, which from the getgo has intention and plans in place to be continually weighing risks and benefits to participants may have the ability to avoid stigma and labeling.